REMARKS

Reconsideration of the objection and rejections set forth in the Office action mailed June 16, 2006 is respectfully requested.

I. Objection under 37 CFR 1.126

37 CFR 1.126 requires that the original numbering of the claims be preserved throughout prosecution. Misnumbered claims 1-10 have been renumbered 37-46 in accordance with the Examiner's suggestion. Withdrawal of the objection is respectfully requested.

II. Rejections under 35 U.S.C. §112, First Paragraph

Claims 37-46 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably covey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner has objected to the claim language directed to "a filmogenic protein."

Claims 37-42 were rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly does not enable the skilled person to make and/or use the invention commensurate in scope with the claims. Specifically, the Examiner alleges that "Applicants have not provided guidance in the specification toward a method of delivering the broad genus of compositions claimed, not a representative number of species thereof, to any tumor site in an organism comprising the administration of microbubbles comprising any filmogenic protein encapsulating insoluble gas microbubbles and further comprising any medicament or biological agent optionally bound to the filmogenic protein and encapsulated within the microbubbles," Office Action mailed June 16, 2006, page 7.

These rejections are respectfully traversed for the following reasons.

At the outset, Applicants note that independent claims 37 and 43 have been amended to specify that the claimed filmogenic protein is selected from the group consisting of albumin, human gamma globulin, human apotransferrin, beta lactase and urease.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by disclosure of relevant identifying characteristics to show the applicant was in possession of the claimed genus. MPEP § 2163 II.A.3.ii. Here, support for use of the term "filmogenic protein" may be found, for example, at page 4, paragraph 7, line 2 of the specification, wherein it is set forth that "[t]he invention employs conjugation of [a] biologic agent with a filmogenic protein which is formed as a protein shell microbubble encapsulating an insoluble gas. The composition is prepared as an aqueous suspension of a plurality of the microbubbles for parenteral administration. Conjugation of the biologic with albumin or other such protein encapsulated microbubbles can allow for targeted delivery of the biologic to alternate including those which traditionally interact with the protein."

Further, in the paragraph bridging pages 7-8, the specification teaches that "[t]he pharmaceutical liquid composition of the invention uses a liquid wherein the microbubbles are stabilized by a filmogenic protein coating. Suitable proteins include naturally occurring proteins such as albumin, human gamma globulin, human apotransferin, Beta lact[a]se and urease. The invention preferably employs a naturally occurring protein but synthetic proteins may also be used. Preferred is human serum albumin."

On page 16, third paragraph, the Specification teaches that the Examples "are for illustration purposes only and are not intended to limit this invention in any way." Further, the Specification indicates that "[i]t will be appreciated by those of skill in the art, that numerous other protein-bioactive agent combinations can be used in the invention and are even contemplated herein. For example, if the filmogenic protein is transferrin, the bioactive agent could be any transferrin binding pharmacologic."

These disclosures indicate that there is sufficient written description to inform a skilled artisan that Applicants were in possession of the claimed invention as a whole at the time the application was filed. In view of the foregoing, Applicants respectfully request that the rejections under 35 U.S.C. §112, first paragraph be withdrawn.

III. Obviousness-Type Double Patenting Rejections

Claims 43-46 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,117,858.

Claims 43-46 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-13 of U.S. Patent No. 5,849,727.

Claims 43-46 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-17 of U.S. Patent No. 6,537,814.

Claims 43-46 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-6 and 8 of co-pending Application No. 10/355,388. Applicants note that the issue fee was paid in this case on July 20, 2006.

A Terminal Disclaimer prepared in accordance with 37 C.F.R. §1.321(b) and (c) is enclosed. The signed Terminal Disclaimer obviates the obviousness-type double patenting rejections and withdrawal of the rejections is respectfully requested.

IV. Conclusion

In view of the foregoing, Applicants respectfully submit that each of the pending claims 1-12 are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4341.

Respectfully submitted,

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